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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,295	09/17/2003	Peter N. Mascia	11696-047001	8833
26191 7590 12/18/2006 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER FOX, DAVID T	
			ART UNIT	PAPER NUMBER
			1638	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/18/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/667,295

Applicant(s)

MASCIA, PETER N.

Examiner

David T. Fox

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28,30-50 and 52-63 is/are pending in the application.
- 4a) Of the above claim(s) 37-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28,30-36,50 and 52-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/12/04 & 9/29/06</u> | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of 26 November 2006 resulted in the cancellation of claims 29 and 51, and the addition of new claims 59-63.

Obviousness-type Double Patenting

Claims 1-28, 30-36, 50 and 52-63 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/873,679. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented in the last Office action on pages 2-3 for claims 1-36 and 50-58.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 26 September 2006 have been fully considered but they are not persuasive. Applicant urges that the double patenting rejection is improper, since the copending application was filed later than the instant application. The Examiner maintains that due to Patent Term Extension, the instant application may issue later than the copending application.

Written Description

Claims 1-28, 30-36, 50 and 52-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention, as stated on pages 3-5 for claims 1-36 and 50-58.

Applicant's arguments filed 26 September 2006 have been fully considered but they are not persuasive. Applicant urges that the specification provides a description of various transcription activators and recognition sequences. Applicant also cites *Capon v. Dudas* to support their position that the written description rejection is improper.

Regarding *Capon*, the Examiner maintains that different fact patterns are involved in the instant application. In *Capon*, the claims encompassed the well-developed antibody art, wherein "over 785 mouse antibody DNA light chains and 1,327 mouse antibody DNA heavy chains were known and published as early as 1991" (see page 10 of *Capon* decision). The instant application involves the art of plant transformation with transcriptional activator-encoding sequences, which art has been demonstrated to be unpredictable, as stated below and in the last Office action.

Enablement

Claims 1-28, 30-36, 50 and 52-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to plant transformation with promoters comprising the yeast Hap1 transcription activator recognition sequence, and with a sequence encoding a chimeric transcription activator protein comprising a yeast Hap1 DNA binding domain and a herpes simplex virus VP16 transcription activator domain; does not reasonably provide enablement for claims broadly drawn to any transcription activator-encoding sequence and with promoters comprising any transcription activator recognition sequence. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on pages 5-7 for claims 1-36 and 50-58 in the last Office action.

Applicant's arguments filed 26 September 2006 have been fully considered but they are not persuasive. Applicant urges that the references cited by the Examiner do not support his case for lack of enablement, because Lloyd et al do not state that their lines were not useful, because Bruce et al demonstrate success in a plant system, and because Schena et al do not represent the current state of the art.

The Examiner maintains that Lloyd et al demonstrate the unpredictability inherent in the process, whether or not they explicitly state that their lines were not useful. Regarding Schena et al, the Examiner maintains that the later-published developments in the art, namely codon optimization of transcription activator-encoding sequences, were not taught in the instant specification. Similarly, Bruce et al was not part of the instant application.

See *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Anticipation

Claims 50, 53-54, 56-58 and new claims 59-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Crossland et al (US 6,362,394 filed 17 August

1999), as stated on pages 7-8 of the last Office action for claims 50-51, 53-54 and 56-58 .

Claims 50, 53-54, 57-58 and new claims 59-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Goff et al (US 6,147,282), as stated on pages 8-9 of the last Office action for claims 50-51, 53-54 and 57-58.

Applicant's arguments filed 26 September 2006 have been fully considered but they are not persuasive. Applicant urges that the art rejections are improper because the references do not teach ligand-independent male sterility, and because the references teach genetic engineering-mediated male sterility rather than the instantly claimed cytoplasmic, nuclear or genetic male sterility.

The Examiner maintains that the references teach that the presence of a nuclear transgene confers male sterility in the absence of an exogenously applied chemical ligand, i.e. under normal field conditions, as admitted by Applicant (see, e.g., page 19 of the Response of 26 September 2006, second full paragraph, last sentence). A nuclear transgene may be considered "nuclear" or "genetic" male sterility. Furthermore, it is noted that Applicant does not actually teach male sterile plants of any kind. See, e.g., page 28 of the specification, line 32 and page 29, line 12, where it is taught that transformed rice plants were selfed. Selfing employs the use of pollen produced by the flower, i.e. the use of a male-fertile flower.

Obviousness

Claims 1-18, 21-28, 30-36, 50 and 52-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Crossland et al (US 6,362,394 filed 17 August 1999)

and Goff et al (US 6,147,282), in view of Harada et al (US 6,781,035 filed 01 March 2000), as stated on pages 10-12 of the last Office action for claims 1-18, 21-36 and 50-58.

Claim 19 remains rejected under 35 U.S.C. 103(a) as being unpatentable over each of Crossland et al (US 6,362,394 filed 17 August 1999) and Goff et al (US 6,147,282), in view of Harada et al (US 6,781,035 filed 01 March 2000), as applied to claims 1-18, 21-28, 30-36, 50 and 52-63 above, further in view of Fischer et al (US 6,906,244), and further in view of Fischer et al (US 6,229,064), as stated on pages 12-13 of the last Office action.

Claim 20 remains rejected under 35 U.S.C. 103(a) as being unpatentable over each of Crossland et al (US 6,362,394 filed 17 August 1999) and Goff et al (US 6,147,282), in view of Harada et al (US 6,781,035 filed 01 March 2000), as applied to claims 1-18, 21-28, 30-36, 50 and 52-63 above, further in view of Fischer et al (US 6,559,357), as stated on pages 14-15 of the last Office action.

Applicant's arguments filed 26 September 2006 have been fully considered but they are not persuasive. Applicant urges that the obviousness rejections are improper, given the failure of the prior art to teach or reasonably suggest the claimed cytoplasmic, nuclear or genetic male sterility; the failure of the primary references to teach seed formation; and the failure of the secondary (or tertiary) references to cure the deficiencies of the primary or secondary references.

The Examiner maintains that the primary references do indeed teach nuclear and genetic male sterility as discussed above. Furthermore, the use of seedlessness, i.e. female sterility, is but one of the options employed by the primary references.

Finally, it is noted that Applicant's evidence of unexpected results relies upon the use of a male fertile rice cultivar which has been transformed with a transgene encoding a single transcription activator-encoding sequence and a single transcription activator recognition sequence. In contrast, the claims are broadly drawn to any transcription activator and its corresponding coding sequence, multiple transcription activators and their coding sequences, any and multiple transcription activator recognition sequences, any plant species, and multiple types of male sterility (none of which have been actually reduced to practice).

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 11, 2006

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

